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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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9/737,542 12/14/00 MILES

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EXAMINER

PADMANABHAN, K

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/737,542

Applicant(s)

MILES ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, drawn to a method for detecting pathogens attached to specific antibodies, classified in class 435, subclass 7.1.
 - II. Claims 10-21, drawn to an apparatus and sensor for determining the presence of pathogens, classified in class 435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, other methods, such as dielectrophoresis (DEP), can be used to collect or concentrate pathogens in an electric field of a fluidic device.
3. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and the search required for one group is not required of the others, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with L.E. Carnahan on April 2, 2001 a provisional election was made with traverse to prosecute the invention of Group II, claims 10-21.

Affirmation of this election must be made by applicant in replying to this Office action. Claims

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1-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The disclosure is objected to because of the following informalities: the application number and filing date of the copending application referred to on page 2 has been omitted. In addition, page 16 of the specification has been omitted

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 15, 17, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. In claim 15, the recitation of "means" is vague and indefinite. Applicant should recite the function of "means" in the claim.

10. In claim 17, applicant should change "forming" to "formed".

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11. In claim 21, the omission of a period at the end of the claim renders the claim vague and indefinite, as it is unclear if text has been omitted at the end of the claim. In addition, claim 21 depends from a non-elected claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 10, 12, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kipling et al. (US Pat. 5,374,521). Kipling et al. disclose a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). Since the sensor of the reference is used for the determination of analytes in a liquid, the positioning of the electrodes is interpreted as being on a surface of a fluidic channel, as a fluidic channel is interpreted as any surface on which a fluid can travel. It is further inherent that the electric field is produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies.

14. Claims 10, 12, 15-16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Stetter et al. (US Pat. 5,567,301). Stetter et al. disclose a biosensor comprising two spaced metal electrodes, wherein at least one antibody is disposed on and/or between the two electrodes. The sensor also comprises impedance detection means for measuring the impedance between the two electrodes (cols. 3-4). Since figure 2 shows the impedance as a function of the AC frequency, the presence of an AC power source for the production of an electric field across the electrodes is inherent. In addition, the electrodes are interpreted as being on a surface of a fluidic channel for reasons discussed above.

15. Claims 10, 12-13, 16, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Clerc (US Pat. 6,133,046). Clerc discloses an apparatus for detecting an analyte in a sample comprising at least one mobile electrode and one fixed electrode opposite the mobile electrode disposed within a fluidic channel. Both electrodes may be coated with a ligand, wherein the ligand may be an antibody to the analyte of interest. The device also comprises means for measuring the impedance between the electrodes (cols. 2-3). The application of voltage to the electrodes creates a magnetic field or electric field around the apparatus. The apparatus may also comprise a second pair of spaced electrodes (col. 10).

16. Claims 10-14, 16-19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (US Pat. 5,001,048). Taylor et al. disclose an electrical biosensor for analyte determination. In one embodiment, a single chip design is used, wherein the transducer is a quartz or glass substrate containing two terminal interdigitated electrodes in a fluidic channel. A receptor (which may be an antibody) containing membrane is in contact with the electrodes. A current is applied across the electrodes creating an electric field, such that a change in impedance

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results upon binding of an analyte to its receptor. The impedance is measured and is indicative of analyte concentration in the sample. In another embodiment, a double chip design may be used. This biosensor includes a non-receptor (reference) membrane and a receptor containing membrane, wherein the membranes are attached to different electrode surfaces, and impedance measured from control membrane is considered as a background signal. A barrier, which may be comprised of an insulator, is located between the reference and receptor-containing electrode to inhibit current flow between the two surfaces. It is once again inherent that the power supply is AC or DC.

17. Claims 10, 12-18, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Vadgama et al. (WO 98/19153). Vadgama et al. disclose a sensor comprising an immobilized affinity component associated with a conducting polymer, such that interaction of the target analyte with the affinity component induces a change in a detectable electrical property. The sensor of the reference also comprises means for applying an AC signal to the polymer and means for detecting the impedance of the polymer (page 2). The affinity component of the sensor may be an antibody. The polymer may be in the form of a layer bridging two electrodes between which the impedance is measured. The two electrodes together may define an interdigitated electrode assembly (page 3). It is inherent that the electrode assembly is located on a surface of a fluid channel.

18. Claims 10, 12-14, 16-18, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Gerwen et al. (WO 97/21094). Van Gerwen et al. disclose an impedimetric detection system comprising an insulating layer with a plurality of interspersed channels therein. A metal coating is applied to one of the two opposite side walls of each channel and on top of the

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dielectric layer in between said channels, thereby forming an impedimetric device. Probes are applied to either the insulating part of the channels or to the surface of the electrodes or both. The device also comprises means for applying a voltage on the metal coatings and measuring the impedance between the electrodes. The sensor of the reference also has an interdigitated electrode structure. The probes of the device include antibodies (page 5 and figures 1-7). When an electric signal is applied (voltage or current), an electric field arises. If the analyte is present in the solution tested, it will be bound to the probe on the electrode surface, resulting in a change in impedance, which is then quantified (page 15). It is inherent that the means for producing the electric field is an AC or DC power supply.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (US Pat. 5,001,048), Vadgama et al. (WO 98/19153), or Van Gerwen et al. (WO 97/21094).

Taylor et al., Vadgama et al., and Van Gerwen et al. teach impedimetric detection systems, as discussed above. However, none of the references teach the use of a plurality of signal generators, a current sensor attached to an electrode, and a plurality of mixer/amplifier assemblies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use means for measuring impedance comprising a plurality of signal generators, a current sensor attached to an electrode, and a plurality of mixer/amplifier assemblies with the devices of Taylor et al., Vadgama et al., and Van Gerwen et al. One would have been motivated to do so because such assemblies were well known in the art at the time of the invention and would have facilitated the concurrent measurement of multiple impedance signals in various phases and at different angles.

Conclusion

Claims 10-21 are rejected.

References: Krueger et al., Willner et al., Giaever et al., Clark et al., Ribi, Janata et al., Malmros et al., Arwin et al., Rishpon et al., Osman et al., Miles et al., Wilkins et al., Kindler, Athey et al.,

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Shanks et al., Gitler et al., Case et al., Hollis et al., Durst et al., Hafeman et al., Board, and Nishiwaki et al. are cited as art of interest to the disclosure of applicants for teaching various electrodes structures for determining the presence of analytes in a sample.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4243 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641


June 18, 2001


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06/18/01